EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, § 413.171 was added, effective January 1, 2011.

§ 413.172 Principles of prospective payment.

(a) Payments for outpatient maintenance dialysis are based on rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered outpatient maintenance dialysis. Approved ESRD facility means—

(1) Any independent or hospital-based facility (as defined in accordance with §§ 413.174(b) and 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008]

EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, § 413.172 was amended by revising paragraph (a), (b) introductory text and paragraph (b)(1), effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

* * * * *

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using the following methodology:

(1) For dialysis services furnished prior to January 1, 2009, the methodology differentiates between hospital-based and independent ESRD facilities;

(2) For dialysis services furnished on or after January 1, 2009—

(i) The composite rate paid to hospital-based facilities for dialysis services shall be the same as the composite rate paid for such services furnished by independent renal dialysis facilities.

(ii) When applying the geographic index to hospital-based facilities, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(3) Effectively encourages efficient delivery of dialysis services; and

(4) Provides incentives for increasing the use of home dialysis.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the

hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in §414.313.

(f) *Additional payment for separately billable drugs.* CMS makes an additional payment for certain drugs furnished to ESRD patients by a Medicare-approved ESRD facility. CMS makes this payment directly to the ESRD facility. Payment for these drugs is made—

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) Effective January 1, 2006, to hospital-based ESRD facilities in accordance with the methodology specified in §414.904 of this subchapter.

(4) To independent ESRD facilities in accordance with the methodology specified in §405.517 of this subchapter.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 69935, Nov. 19, 2008]

EFFECTIVE DATE NOTE: At 75 FR 49198, Aug. 12, 2010, §413.174 was amended by revising paragraphs (a), (f) introductory text and (f)(3) and (4) and adding paragraph (f)(5), effective January 1, 2011, and by adding paragraph (f)(6), effective January 1, 2014. For the convenience of the user, the added and revised text is set forth as follows:

§413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

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(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

* * * * *

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in §414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in §405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in §414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in §413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2014, payment to an ESRD facility for renal dialysis service drugs

and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

§ 413.176 Amount of payments.

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary pays the facility 80 percent of its prospective payment rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, the intermediary subtracts the amount applicable to the deductible from the facility's prospective rate and pays the facility 80 percent of the remainder, if any.

EFFECTIVE DATE NOTE: At 75 FR 49199, Aug. 12, 2010, § 413.176 was revised, effective January 1, 2011. For the convenience of the user, the revise text is set forth as follows:

§ 413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

§ 413.178 Bad debts.

(a) CMS will reimburse each facility its allowable Medicare bad debts, as defined in § 413.89(b), up to the facility's costs, as determined under Medicare principles, in a single lump sum payment at the end of the facility's cost reporting period.

(b) A facility must attempt to collect deductible and coinsurance amounts owed by beneficiaries before requesting reimbursement from CMS for uncollectible amounts. Section 413.89 specifies the collection efforts facilities must make.

(c) A facility must request payment for uncollectible deductible and coinsurance amounts owed by beneficiaries by submitting an itemized list that specifically enumerates all uncollectable amounts related to covered services under the composite rate.

(d) Bad debts arising from covered ESRD services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 47489, Aug. 12, 2005; 71 FR 69785, Dec. 1, 2006]

EFFECTIVE DATE NOTE: At 75 FR 49199, Aug. 12, 2010, § 413.178 was amended by revising paragraph (d), effective January 1, 2011. For the convenience of the user, the revised text is set forth as follows:

§ 413.178 Bad debts.

* * * * *

(d) *Exceptions.* (1) Bad debts arising from covered ESRD services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For services furnished on or after January 1, 2011, bad debts arising from covered ESRD items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a pediatric ESRD facility projects on the basis of prior year costs and utilization trends that it has an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable to one or more of the factors in § 413.182, the facility may request, in accordance with paragraph (e) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.